

# NCI's Evolving Clinical Trials System

## *NCI Community Oncology Research Program (NCORP)*

### Clinical Trials & Translational Research Advisory Board

November 12, 2014

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Division of Cancer Prevention

In Collaboration with NCI's Divisions of Cancer Control and Population  
Sciences and Cancer Treatment & Diagnosis, and the  
Center to Reduce Cancer Health Disparities

# NCORP Milestones

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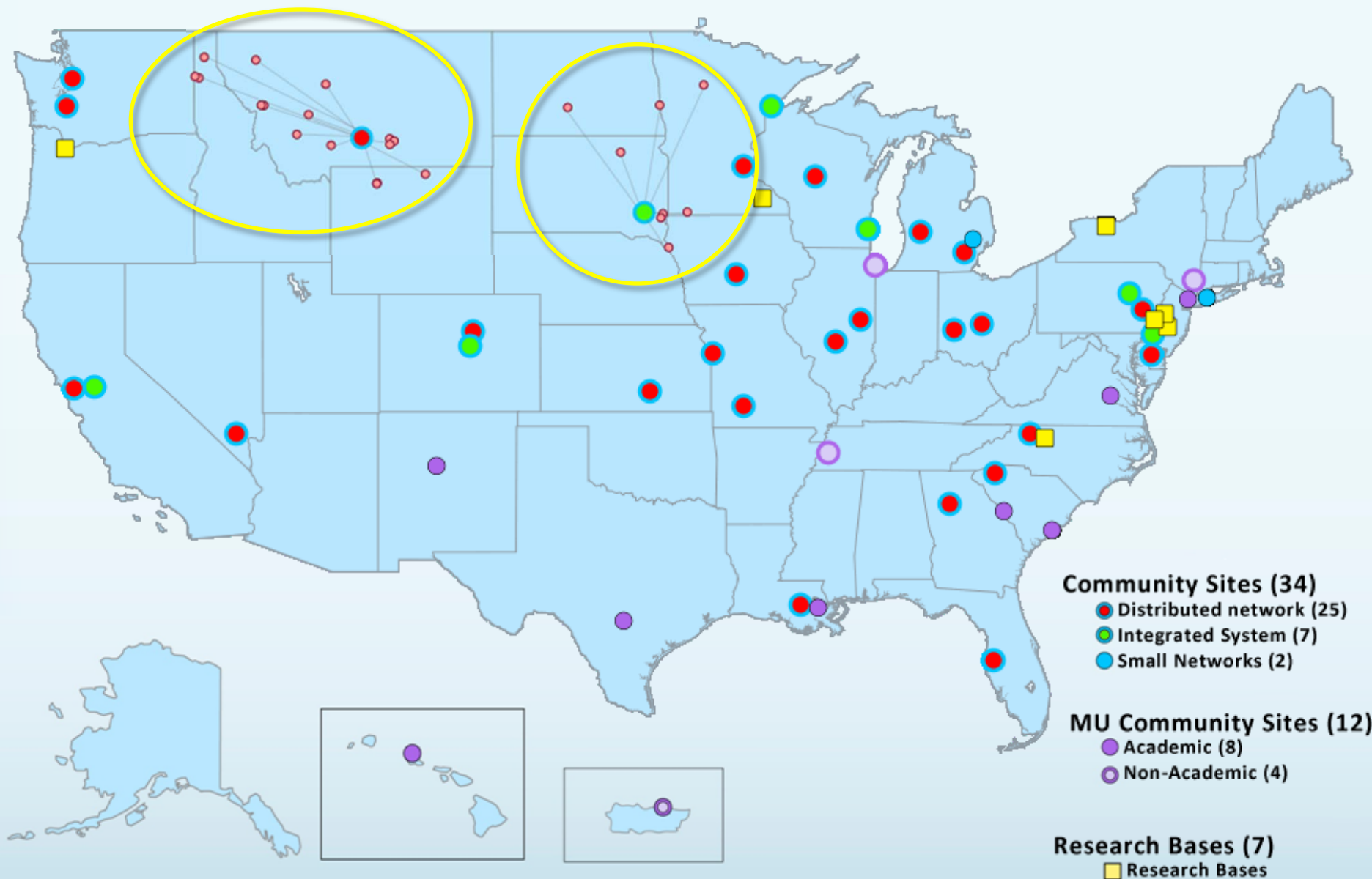
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- April 2012** ● NCI begins the planning of a single community-based research program – NCI Community Oncology Research Program (NCORP).
  - May 2013** ● NCI Scientific Leadership approves the NCORP concept.
  - June 2013** ● Board of Scientific Advisors approves the NCORP concept
  - November 2013** ● The NCORP Funding Opportunity Announcement released with a due date of January 8, 2014.
  - April- May 2014** ● Peer Reviews of NCORP Applications
  - August 1, 2014** ● NCORP Launch
  - August 25-26, 2014** ● Research Base CCDR Meeting
  - September, 22, 2014** ● Welcome NCORP Investigators and Administrators

# **NCORP: A Single Community-Based National Network**

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- **Clinical Trials: prevention, control, health-related quality of life, comparative effectiveness, and screening**
- **Cancer care delivery research: patient-provider and organization-level influences on cancer outcomes**
- **Incorporation of cancer disparities research into clinical trials and cancer care delivery research**
- **Accrual to National Clinical Trials Network (NCTN) treatment and imaging trials**
- **Community/academic partnerships**
- **3 components: Community Sites, Minority/Underserved Community Sites, and Research Bases**

# NCORP Community Site, MU Community Site and Research Bases Geographic and Organizational Diversity



# **NCORP Network Characteristics**

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- **842 Components and Subcomponents**
- **Health Care Systems**
  - **Kaiser, Essentia, Aurora, Catholic Health Initiatives, Geisinger, Sanford & Nemours**
- **7 Merged Community Programs**
- **200+ CCDR Components within 46 Programs**

# NCORP Clinical Trials and Health-Related Quality of Life Studies

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Type	Focus
Cancer Prevention	Identify/evaluate interventions to reduce cancer risk and incidence
Cancer Control	Reduce incidence/co-morbidity of cancer and its treatment, enhance quality of life
Cancer Screening	Evaluate early diagnosis interventions and cancer recurrence
Health-Related Quality of Life	Embedded in NCTN Treatment Trials

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	Research Bases		
	Research Base Applicant	Institution (PI)	Research Focus & Strengths
	Alliance	Mayo Clinic (Jan Buckner)	Chemoprevention risk assessment methods, tobacco harm reduction, disparities, natural history and risk identification of treated-related toxicities
	SWOG	Oregon Health & Science University (Charles Blanke, Dawn Hershman, Frank Meyskens, Catherine Tangen)	Biorepositories for prevention, Comparative effectiveness research
	NRG	NRG Oncology Foundation, Inc. (Deb Bruner, Joan Walker, Larry Wickerham)	Risk reduction of women’s cancers, radiation neurotoxicities, surgically-induced sequelae
	ECOG-ACRIN	ECOG-ACRIN Medical Research Fo. (Lynn Wagner, Mitchell Schnall)	Imaging science, patient reported outcomes, symptom database
	COG	Children's Hospital of Philadelphia (Brad Pollock, Lillian Sung)	Cancer-related infection, neurological sequelae, adolescents and young adults
	URCC	University of Rochester (Gary Morrow)	Cancer-related fatigue in the elderly, treated-related cognitive dysfunction
	Wake Forest	Wake Forest U. Health Sciences (Glenn Lesser, James Urbanic)	Cardiotoxicity, radiation-related toxicities, transitions in care

# **Research Agenda for Cancer Prevention, Control & Screening Trials**

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- **Mechanisms of cancer-related symptoms**
- **Biomarkers of risk for treatment-related toxicities**
- **Molecularly targeted agents**
- **Post-treatment surveillance**
- **Management of precancerous lesions**
- **Enhance accrual of racial/ethnic and other under-represented populations**
- **Over-diagnosis and under-diagnosis**



# **NCORP**

## **Health-Related Quality of Life Steering Committee**

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- **Co-Chairs**
  - Karen Mustian (URCC)
  - Deb Barton (U of Michigan)
- **Added Subject Matter Experts**
  - Food and Drug Administration
  - Pharmacologist
- **New Activities**
  - Working group to explore funding for mechanistic studies for symptom management
  - Webinars to focus on design and patient reported outcomes

# NCORP Clinical Trials

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- **49 clinical trials now active or approved**
  - **Legacy trials from CCOP network including MDAs/Suncoast**
  - **Approved & previously on hold trials**
  - **Actively reviewing new concepts**
- **Task Forces to advance agenda for treatment or cancer–related toxicities (e.g., cardio-oncology)**
- **DCP is conducting webinars to introduce DCTD's precision clinical trials to community sites**

# NCORP

## CCDR Study Types

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NCI conceptualizes three major categories of studies:

- **Descriptive observational studies** to document the prevalence and variability of specific cancer care delivery models, approaches and/or processes
- **Analytical observational studies** to understand how the multi-level characteristics of care delivery models, approaches and processes influence quality, outcomes and access
- **Interventional studies**, including RCT designs, to test new models, approaches and/or processes of care delivery to improve quality, outcomes and access.

# **Cancer Disparities Research**

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- **Expertise from NCI's Center to Reduce Cancer Disparities**
- **DCP is the lead for the AACR-ASCO- ACS-NCI Joint Position Statement on Cancer Disparities Research**
- **Opportunities for Trans-Research Base Collaborations**
  - **Integration of research questions into clinical trials and cancer care delivery studies**

# NCORP FY 2014 Budget

## NCORP Funding

**Grand Total: \$97.0 Million**

\$91.1 Million allocation for NCORP grants

\$ 2.0 Million from DCCPS for NCORP grants (Additional FY 2014 NCI Funding)

\$ 93.1 Million

\$ *3.9 Million allocation for contract support for NCORP*

## Details of NCORP Grant Funding

<i>NCORP Component</i>	<i>No. of Sites</i>	<i>Clinical Trials \$ Millions</i>	<i>CCDR Funding \$Millions</i>	<i>FY 2014 Total</i>
<b><i>NCORP &amp; NCORP-M/U Sites SUBTOTAL:</i></b>	<b><i>46</i></b>	<b><i>\$42.7</i></b>	<b><i>\$ 7.5</i></b>	<b><i>\$50.3</i></b>
<b><i>NCORP Research Bases</i></b>	<b><i>7</i></b>	<b><i>\$38.2</i></b>	<b><i>\$ 4.5</i></b>	<b><i>\$42.8</i></b>

## NCORP Supplemental Funding For Accrual

**\$5.2 M**

# **Cancer Care Delivery Research (CCDR) Planning Meeting**

## **August 25-26, 2014**

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- **Purpose: Begin foundational work for CCDR activities**
  - **Initiate process to develop CCDR strategic priorities**
  - **Prepare for the formation of Coordinating Committee**
  - **Begin discussions surrounding data infrastructure**
- **Attendees:**
  - **Research Base PIs and CCDR Leads**
  - **CCDR Leads from Community & Minority/Underserved Sites with enhanced CCDR capabilities**
- **Research Bases presented their CCDR research priorities and capacities**
  - **Clear evidence of innovation & expertise**
- **NCI presented “CCDR landscape” from national reports**
- **Four breakout discussions**
  - **Disparities, organization and system science, patient engagement, ‘omics’ in clinical practice**

## NCORP Research Bases

Research Base Applicant	Institution	CCDR Leads
Alliance	Mayo Clinic Jan Buckner	Caprice Greenberg, MD George Chang, MD
SWOG	Oregon Health & Science University Charles Blanke	Dawn Hershman, MD Scott Ramsey, MD, PhD
NRG	NRG Oncology Foundation, Inc. Deb Bruner	Joe Lipscomb, PhD
ECOG-ACRIN	ECOG-ACRIN Medical Research Fo. Lynn Wagner	Ruth Carlos, MD
COG	Children's Hospital of Philadelphia Brad Pollock	Lillian Sung, MD, PhD
URCC	University of Rochester Gary Morrow	Supriya Mohile, MD
Wake Forest	Wake Forest U. Health Sciences Glenn Lesser	Kate Weaver, PhD

# CCDR Coordinating Committee

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- Promotes and coordinates **cross-NCORP scientific collaboration**
- Develops **operational procedures** for the development, review and implementation of CCDR within NCORP
- **Standardizes** various aspects of CCDR
  - Data definitions
  - Collection tools and procedures
  - Audit requirements
- Determines data infrastructure to support CCDR



# **Coordinating Committee Membership**

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- **Co-chairs:**
  - Jan Buckner ( Mayo Clinic, Alliance)
  - Ruth Carlos ( U. Mich., ECOG-ACRIN)
  - Scott Ramsey (Fred Hutchinson Cancer Center, SWOG)
- **Two representatives from each Research Base including at least one CCDR expert**
- **Four NCORP Community Sites representatives**
- **Three NCORP Minority/Underserved Site representatives**
- **NCI representatives**

# NCORP CCCR Steering Committee Objectives

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- Set **strategic scientific priorities** for CCCR in the community-setting, including priorities generated across NCORP collaborations
- Provide rigorous **scientific reviews** for CCCR concepts
- Facilitate the uptake of evidence-based clinical outcomes from clinical trials
  - Dissemination & Implementation Research
  - Accelerate the transition of CCCR studies into practice simultaneously

# **NCORP**

## **CCDR Steering Committee Membership**

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- **Co-Chairs**
  - Paul Godley (UNC Chapel Hill)
  - Brad Pollock (UC Davis and COG)
- **NCORP Research Bases**
  - 2 representatives per NCORP Research Bases (1 vote/Research Base)
- **Subject Matter Experts – up to 8 representatives (vote/Expert)**
  - Health Service Research
  - Health Information Technology
  - Health Economist
  - Health Disparities
- **NCORP Community Sites – 2 representatives (2 votes)**
- **Minority/Underserved Community Sites – 2 representatives (1 vote)**
- **Biostatisticians, Statisticians – 2 representatives (1 vote)**
- **Patient Advocates – 2 representatives (1 vote)**
- **NCI Staff (DCCPS, DCP, CRHD) – ( 3 votes)**

# **Early Next Steps for Cancer Care Delivery Research**

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- **Complete the vetting process for the CCDR scientific Steering Committee**
- **Begin process for identifying CCDR research priorities and initiating working groups**
- **Characterize the health care environments and capacities for CCDR across NCORP**

# **How Do Community Investigators Contribute to NCI's Research Mission?**

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- **Membership on Research Base Scientific Committees**
- **NCI's Disease & non-Disease Steering Committees and Task Forces**
- **Membership on Clinical Trials & Translational Research Advisory Committee**
- **NCI Advisory Boards Activities (e.g., National Cancer Advisory Board's Symposium - "NCI's Evolving Clinical Trials System")**
- **Scientific Working Groups (.e.g., Natural Experiments to develop research designs in the area of policy change and their effects on care and health outcomes)**

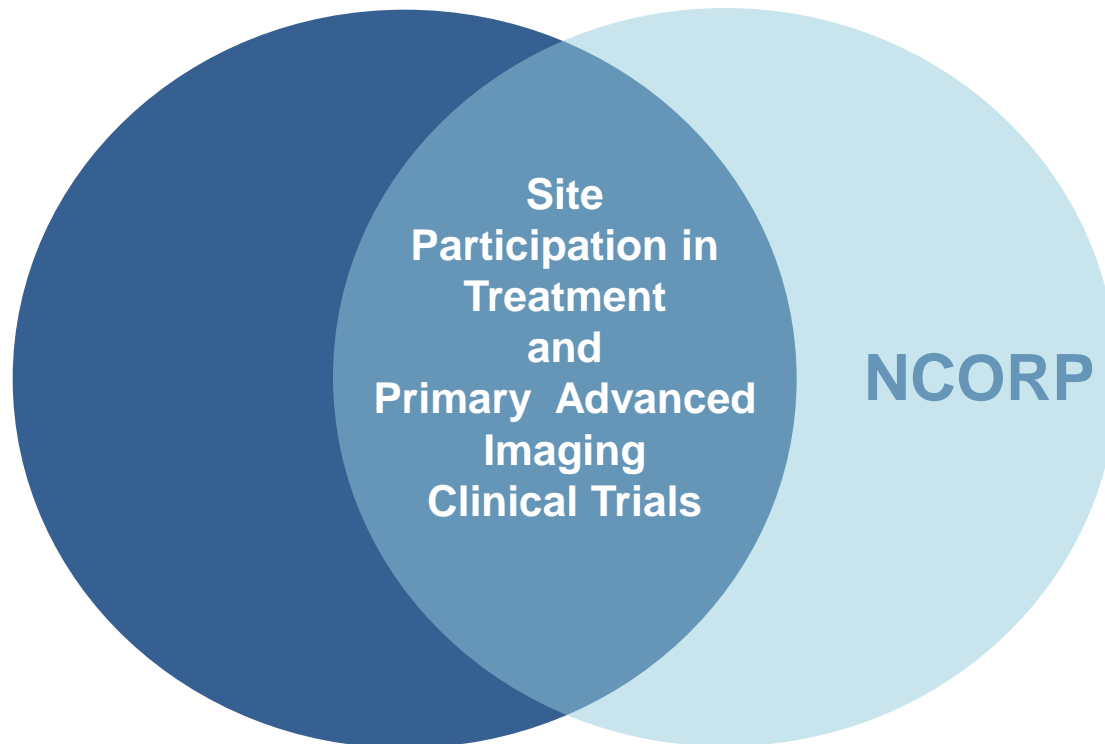
# Relationship of NCTN and NCORP

## **NCTN Focus:**

- Late-Phase Treatment Trials
- Primary Advanced Imaging Trials

## **NCORP Focus:**

- Cancer Prevention and Control Trials
- Cancer Care Delivery
- Comparative Effectiveness Research



**NCTN/NCORP CENTRALIZED FUNCTIONS:**  
CTSU, Study Monitoring  
CIRB: Cancer Prevention and Control (2015)

# **NCORP: Advantages of a New Community-Based Research Organization**

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- **Represents the “real world” of oncology practices**
- **Responsive to extensive stakeholder input**
- **Community Sites & Research Bases are better prepared to support the scientific agenda of NCORP**
- **Capacity to sustain or improve clinical trials accrual to all components of NCTN**
- **Broader base of individuals at risk of cancer**
- **Opportunity to evaluate the influence of the current health care system on the successful conduct and implementation of precision cancer therapy**

***Thank you!***

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